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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,958	05/10/2001	David A. Sirbasku	1944-00201	5333
23505	7590	10/03/2003		
CONLEY ROSE, P.C. P. O. BOX 3267 HOUSTON, TX 77253-3267			EXAMINER HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/852,958

Applicant(s)
Sirbasku

Examiner
Harris

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 10, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-108 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. Claims 1-108 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

It is noted that claim 86 is drawn to "The in vitro cell culture model of claim 66.....". However a review of claim 66 reveals that the claim is drawn to a kit comprising a population of cultured cells, an immunoglobulin inhibitor, a serum-free culture medium. On the other hand, claims 75-85 are drawn to an in vitro cell culture model. Therefore, in the interests of compact prosecution, it is reasonable to assume that claim 86 is meant to be dependent upon one of claims 75-85 and thus claim 86 has been grouped with those claims. Appropriate correction of the improper dependency is required.

Group 1. Claims 1-17, 19-20, 27, 30, 33 are drawn to an inhibitor of in vitro cancer cell proliferation classified in Class 530, subclass 387.1.

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Group 2. Claim 18 drawn to a method of making a steroid hormone reversible cancer cell growth inhibitor composition classified in Class 530, subclass 387.1.

Group 3. Claim 21 is drawn to a negative serum composition, classified in Claws 530, subclass 387.1.

Group 4. Claims 22-23 are drawn to method of making a negative serum composition, classified in Class 530, subclass 387.1.

Group 5. Claims 24-26 are drawn to a control serum concentration, classified in Class 530, subclass 387.1.

Group 6. Claims 28-29 are drawn to a method of making a substantially steroid hormone-depleted serum, classified in Class 530, subclass 387.1.

Group 7. Claim 31 is drawn to a different method of making a substantially steroid hormone-depleted serum, classified in Class 530, subclass 387.1.

Group 9. Claim 32 is drawn to a method of making a purified immunoglobulin inhibitor, classified in Class 530, subclass 387.1.

Group 10. Claims 34-43 are drawn to an in vitro method for detecting steroid hormone-like cancer cell growth stimulation, classified in Class 435, subclass 4.

Group 11. Claim 44 is drawn to a method of determining a steroid hormone antagonistic substance, classified in Class 435, subclass 4.

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Group 12. Claims 45-55 are drawn to a culture medium, classified in Class 435, subclass 253.6.

Group 13. Claim 56 is drawn to an in vitro method of culturing cancer cells, classified in Class 435, subclass 253.6.

Group 14. Claim 57 is drawn to an in vitro method of detecting a cell growth stimulatory effect classified in Class 435, subclass 4.

Group 15. Claims 57-58 are drawn to an in vitro method of detecting a cell growth inhibitory effect classified in Class 435, subclass 4.

Group 16. Claims 59-61 are drawn to a method of producing a biomolecule classified in Class 435, subclass 252.3.

Group 17. Claims 63-69 are drawn to an assay kit classified in Class 435, subclass 810.

Group 18. Claims 70-72 are drawn to a method of measuring the amount of steroid hormone reversible inhibitor in a sample of body fluid, classified in Class 435, subclass 4.

Group 19. Claims 73-74 are drawn to a an in vitro method of detecting an immunoglobulin inhibitor in a sample, classified in Class 435, subclass 4.

Group 20. Claims 75-86 are drawn to an in vitro cell model classified in Class 435, subclasses 4, 325.

Group 21. Claims 87-92 are drawn to a cell line, classified in Class 435, subclass 325.

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Group 22. Claim 93-94 is drawn to a mediator of estrogen responsiveness, the estrogen receptor gamma, Classified in Class 530, subclass 350+.

Group 23. Claims 95-98 are drawn to a method of detecting an estrogenic substance, classified in Class 435, subclass 4.

Group 24. Claims 99-101 are drawn to a method of detecting an anti-estrogenic substance, classified in Class 435, subclass 4.

Group 25. Claims 102 is drawn to identifying an estrogen responsive cell, classified in Class 435, subclass 4.

Group 26. Claims 103-107 are drawn to a different method of inhibiting/killing cancer *in vitro*, classified in Class 514, subclass 2.

Group 27. Claim 108 is drawn to a method of measuring the concentration of steroid hormone, classified in Class 435, subclass, 4.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 3, 5, 12, 17, 20, 21, 22 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 2, 4, 6-11, 18-19, 23-27 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

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The inventions of Groups 1/3/5/17/20 and 2-11/13-15, 18, 19 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the inhibitor product as claimed can be used in a materially different process such as an antigen for production of antibodies against the inhibitor. The ingredients of the assay kit can be used as antigens for production of antibodies. The cell model can be used to identify the metabolic pathways of the cells in the model.

The inventions of Groups 12 and 13 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the culture medium as claimed can be used to culture other types of cells.

The inventions of Groups 22 and 23/24/25 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the

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instant case the mediator can be used in a materially different process such as an antigen for production of antibodies.

The inventions of Groups 26-27 do not appear to be related to any of the claimed products as the claimed products do not appear to be used in the methods of Groups 26-27.

The inventions of Groups 1/3/5/12/17/20/22 do not appear to be related to any of the other claimed methods as the claimed products do not appear to be used in the other claimed methods.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana Harris, PhD whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

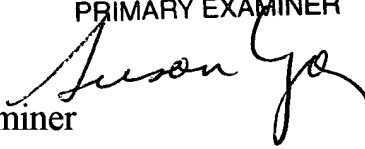
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Alana Harris, PhD
Primary Patent Examiner
September 30, 2003

A handwritten signature in cursive script, appearing to read "Susan Ungar", is written over the printed name and title of the Primary Examiner.